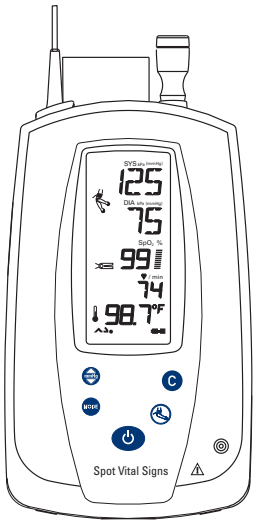
Welch Allyn Spot Vital Signs



Directions for Use

REF 420 Series

Welch Allyn®

Advancing Frontline Care™

CAUTION: United States Federal Law restricts this device to sale by or on the order of a health care practitioner.

Welch Allyn Spot Vital Signs

Directions for Use

Welch Allyn®

Advancing Frontline Care™

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For information about any Welch Allyn product, call Welch Allyn Technical Support:

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European Call Center	+353 46 90 67790	France	+33 1 55 69 58 49
Germany	+49 7477 9271 70	Japan	+81 3 3219 0071
Latin America	+1 305 669 9003	Netherlands	+31 157 505 000
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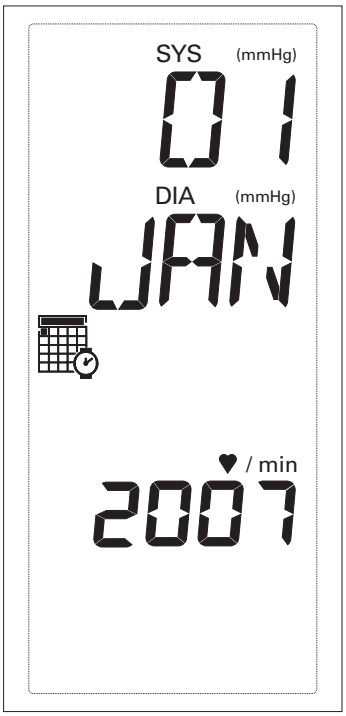
Welch Allyn®
Advancing Frontline Care™

Configuration

After recharging a dead battery or after disconnecting the battery for a few minutes, you must program the date and time screen. See page 19 for more details.



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1 Introduction

This manual is designed to help you understand the capabilities and operation of your Welch Allyn Spot Vital Signs. The information in this manual includes all options available with the Spot Vital Signs (e.g., SpO_2, temperature, mobile stand, and wall mount). The applicability of some sections of this manual depends on the configuration of your particular unit. Read this manual thoroughly before attempting to use the device.

Table 1. Available Versions of Spot Vital Signs

REF	Description
4200B	Spot Vital Signs with blood pressure only
420TB	Spot Vital Signs with blood pressure and SureTemp thermometer
42MOB	Spot Vital Signs with blood pressure and Masimo SpO_2
42NOB	Spot Vital Signs with blood pressure and Nellcor SpO_2
42MTB	Spot Vital Signs with blood pressure, SureTemp thermometer, and Masimo SpO_2
42NTB	Spot Vital Signs with blood pressure, SureTemp thermometer, and Nellcor SpO_2

Product Overview

The Welch Allyn Spot Vital Signs non-invasively and automatically measures systolic and diastolic blood pressure, pulse rate, and oxygen saturation (SpO_2) for adult and pediatric patients. Further, the Welch Allyn Spot Vital Signs measures temperature invasively in natural body orifices (i.e., mouth and rectum).

THE WELCH ALLYN SPOT VITAL SIGNS IS NOT INTENDED FOR USE ON NEONATAL PATIENTS.

All blood pressure, pulse, temperature, and SpO_2 values are viewed on a large, easy-to-read display.

The rechargeable lead acid battery and variety of mounting accessories make the Welch Allyn Spot Vital Signs convenient for many locations. You may choose any combination of simultaneous measurement modalities.

The Welch Allyn Spot Vital Signs can be used in a wide variety of health care settings. This includes hospital departments as well as alternate care settings such as physicians' offices, clinics, and long-term care facilities. The Welch Allyn Spot Vital Signs is not intended for continuous monitoring of patients, nor for use during the transport of a patient. The Welch Allyn Spot Vital Signs is not intended for use in environments that are not supervised by a health care practitioner.

Related Publications

Masimo Directions for Use - for models 42M0B and 42MTB

Nelcor Directions for Use - for models 42N0B and 42NTB

Indications/Contraindications for Use

The Welch Allyn Spot Vital Signs measures blood pressure, pulse rate, temperature, and SpO_2 of adult and pediatric patients. The device is not designed, sold, nor intended for use other than previously stated.

THE WELCH ALLYN SPOT VITAL SIGNS IS NOT INTENDED FOR USE ON NEONATAL PATIENTS.

To ensure pediatric blood pressure accuracy and safety, the Welch Allyn Child Print Cuff (5200-03), the Welch Allyn Small Child Durable One-Piece Cuff (5082-203-3), and the Welch Allyn Small Child Disposable One-Piece Cuff (5082-93-3) are the smallest cuffs allowed for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

The Welch Allyn Spot Vital Signs is FDA cleared to measure the axillary temperature in normal mode for children under the age of 4.

The Welch Allyn Spot Vital Signs is not intended for continuous monitoring and is therefore not defibrillator proof. **Do not leave the device unattended while taking measurements on a patient.**

The Welch Allyn Spot Vital Signs should not be used on patients who are linked to heart/lung machines.

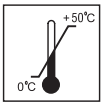
Symbols and Descriptions

Familiarize all operating personnel with the general safety information in this summary. Operators will also find specific warnings and cautions throughout the Directions for Use. Such specific warnings and cautions may not appear here in this summary.

Caution: Consult manual for additional information.

Type BF Equipment

Handle with Care



Transport Temperature

Storage Humidity

Internally Powered, Lead Acid Battery.

Class II Equipment

IPXØ Not protected against the ingress of water.

Mode of Operation: Continuous

Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply.

For more specific disposal information, see www.welchallyn.com/weee, or contact Welch Allyn Customer Service at +44 207 365 6780.

Safety Warnings and Cautions

All operating personnel should be familiarized with the general safety information in this summary. Specific warnings and cautions are also found throughout this manual. Such specific warnings and cautions may not appear here in this summary.

General Warnings

A warning statement in this manual identifies a condition or practice, which if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

WARNING The Welch Allyn Spot Vital Signs is designed for use by medical clinicians. Although this manual may illustrate medical spot check techniques, only a trained clinician who knows how to take and interpret a patient's vital signs should use this system.

WARNING The information in this manual is a comprehensive guide to the operation of the Welch Allyn Spot Vital Signs. To achieve satisfactory results, you should read the manual thoroughly before attempting to use the device.

WARNING Spot Vital Signs is not intended to take measurements on neonatal patients. The AAMI SP10:1992 standard defines neonates as children 28 days or less of age if born at term (37 weeks gestation or more); otherwise up to 44 gestational weeks.

WARNING The Welch Allyn Spot Vital Signs is not defibrillator proof.

WARNING The Welch Allyn Spot Vital Signs is not intended for continuous monitoring. Do not leave the device unattended while taking measurements on a patient.

WARNING To ensure patient safety, use only accessories and supplies (i.e., blood pressure cuffs, hoses, temperature probes, SpO_2 sensors, etc.) recommended for or supplied with Spot Vital Signs. Using unapproved accessories with Spot Vital Signs can affect patient and/or operator safety.

WARNING This device is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.

WARNING Avoid compression of the blood pressure cuff tubing or pressure hose of the Welch Allyn Spot Vital Signs. Compression of the cuff tubing or pressure hose may cause system errors to occur in the device.

WARNING Care should be taken to prevent water or other fluid from entering any connectors on the device. Should this occur, the connectors should be dried with warm air. All operating functions should then be checked for proper operation.

WARNING Any Spot Vital Signs which has been dropped or damaged should be checked by qualified service personnel to ensure proper operation prior to use. Do not use the Welch Allyn Spot Vital Signs if you notice any signs of damage. Contact the Welch Allyn Customer Service Department for assistance.

WARNING Every three months, inspect the temperature probe, SpO_2 cord, and accessories for fraying or other damage. Replace as necessary.

WARNING There are no user-serviceable parts inside the device other than battery replacement. Refer Spot Vital Signs to the Authorized Service Center.

WARNING The Spot Vital Signs should not be used on patients who are linked to heart/lung machines.

WARNING The Spot Vital Signs does not operate effectively on patients who are experiencing convulsions or tremors.

WARNING This device complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

WARNING This device is not intended for hand-held use during operation.

WARNING Welch Allyn recommends leaving the battery in the device, regardless if the device is not used for long periods of time, since there is no hazard of leaving the battery in the device.

WARNING Do not autoclave.

WARNING Welch Allyn is not responsible for the integrity of any mounting installation. Welch Allyn recommends that the customer contact their Biomedical Engineering Department or maintenance service to ensure professional installation for safety and reliability of any mounting accessory.

Blood Pressure Warnings

WARNING To ensure pediatric blood pressure accuracy and safety, the Welch Allyn Child Print Cuff (5200-03), the Welch Allyn Small Child Durable One-Piece Cuff (5082-203-3), and the Welch Allyn Small Child Disposable One-Piece Cuff (5082-93-3) are the smallest cuffs allowed for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

WARNING You may experience inaccurate blood pressure measurements if blood pressure cuffs and/or hoses other than those provided by Welch Allyn for the Spot Vital Signs are used.

WARNING Patients who are experiencing moderate to severe arrhythmias may give inaccurate blood pressure measurements.

WARNING When several blood pressure measurements are taken on the same patient, it is recommended that the blood pressure cuff site and extremity are checked regularly for possible ischemia, purpura, and/or neuropathy.

WARNING Do not change the connector(s) on the blood pressure cuff tubing of this device to luer type. Luer type connectors are commonly used in intravenous infusion systems. Using the luer connectors on blood pressure cuff tubing creates the risk that the blood pressure tubing could be mistakenly connected to a patient's intravenous line, resulting in the introduction of air into the patient's circulatory system.

SpO_2 Warnings

WARNING Only use Spot Vital Signs with Masimo or Nellcor SpO_2 option with Masimo or Nellcor brand sensors and accessories, respectively. Using the wrong or unapproved sensors or cables may cause improper performance.

WARNING The SpO_2 sensors and extension cables are intended for use only for pulse oximetry measurements. Do not attempt to connect these cables to a PC or any similar device.

WARNING Before use, carefully read the sensor's directions for use, including all warnings, cautions, and instructions.

WARNING Do not use a damaged sensor or SpO_2 cable. Do not use a sensor with exposed optical components.

WARNING Tissue damage can be caused by incorrect application or duration of use of an SpO_2 sensor. Inspect the sensor site as directed in the sensor's Directions for Use.

WARNING Do not use the sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the pulse oximetry measurements.

WARNING Certain ambient environmental conditions, sensor application errors, and certain patient conditions may affect SpO_2 readings and pulse signal.

WARNING Do not immerse the sensor or patient cables in water, solvents, or cleaning solutions (the sensors and connections are not waterproof). Do not use irradiation, steam, or ethylene oxide for sterilization.

WARNING Do not use the SpO_2 cable or power cord to lift the unit because the cable or cord could disconnect from the unit, causing the unit to drop on the patient.

WARNING The SpO_2 in the Welch Allyn Spot Vital signs is not intended for use as an apnea monitor.

WARNING Consider the SpO_2 an early warning device. As a trend toward patient deoxygenation is indicated, use laboratory instruments to analyze blood samples to completely understand the patient's condition.

Temperature Warnings

WARNING Single-use, disposable probe covers, available from Welch Allyn, limit patient cross-contamination. The use of any other probe cover or the failure to use a probe cover may produce temperature errors and is specifically not recommended.

WARNING Use only oral probes (blue cap) for taking oral and axillary temperatures. Use only rectal probes (red cap) for taking rectal temperatures. The use of the wrong probe may produce temperature errors.

WARNING Do not allow the tip of the temperature probe to come into contact with any heat source (e.g., hands or fingers) prior to taking a temperature measurement. If this occurs, discard the probe cover and start the temperature determination again.

WARNING Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.

IR Communications Port Warnings

WARNING The Welch Allyn Spot Vital Signs contains an infrared communications port for isolated communications with external devices. The port is located on the side of the device to preclude direct eye contact on a continual basis when viewing the display. As a precaution, do not look directly into the infrared port during operation.

General Cautions

A caution statement in this manual identifies a condition or practice, which if not corrected or discontinued immediately, could lead to equipment failure, equipment damage, or data loss.

Caution If the accuracy of any measurement is in question, check the patient's vital sign(s) by an alternate method, then check to make sure the device is functioning properly.

Caution Ensure the device is placed on a secure surface or use one of the optional mounting accessories.

Caution Do not place fluids on the device.

Blood Pressure Cautions

Caution Extremity and blood pressure cuff motion should be minimized during blood pressure determinations.

Caution If the blood pressure cuff is not at heart level, the difference in reading due to the hydrostatic effect should be noted. The value of 1.80 mmHg must be added to the displayed reading for every inch (2.5 cm) above heart level. The value of 1.80 mmHg must be subtracted from the displayed reading for every inch (2.5 cm) below heart level.

Caution Proper blood pressure cuff size and placement is essential to the accuracy of the blood pressure determination. See "Chart for Determining Blood Pressure Cuff Size" on page 23 for blood pressure cuff sizing information.

Caution When measuring blood pressure on children younger than 3 years of age, it is recommended that the Pressure Preset (initial inflation pressure) be set at 160 mmHg or lower.

SpO_2 Cautions

Caution The pulse oximeter is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.

Caution Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

Caution Some sensors may not be appropriate for a particular patient. If at least 15 seconds of perfusion pulses cannot be observed for a given sensor, change sensor location or sensor type for perfusion to resume.

Caution When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring.

Temperature Cautions

Caution The Welch Allyn Spot Vital Signs is FDA cleared to measure the axillary temperature in Normal Mode for children under the age of 4. Normal Mode axillary temperatures may not be accurate on older children or adults. *THE WELCH ALLYN SPOT VITAL SIGNS IS NOT INTENDED TO BE USED ON NEONATAL PATIENTS.*

Avertissements et précautions de sécurité

Tout le personnel l'utilisant doit être familiarisé avec les informations globales de sécurité contenues dans ce résumé. Ce manuel comprend également des avertissements et précautions spécifiques. Il est possible que ces avertissements et précautions spécifiques ne soient pas indiqués dans ce résumé.

Avertissements généraux

Les avertissements de ce manuel identifient les conditions ou pratiques qui, si elles ne sont pas corrigées ou arrêtées immédiatement, risquent de provoquer des blessures, des maladies ou le décès du patient.

AVERTISSEMENT Le Welch Allyn Spot Vital Signs est conçu pour être utilisé par des médecins. Si ce manuel présente des techniques de vérification médicale ponctuelle, seul un clinicien formé sachant comment relever et interpréter les signes vitaux d'un patient doit utiliser ce système.

AVERTISSEMENT Les informations contenues dans ce manuel sont un guide détaillé du fonctionnement du Welch Allyn Spot Vital Signs. Pour obtenir des résultats satisfaisants, merci de lire ce manuel attentivement avant d'essayer d'utiliser l'appareil.

AVERTISSEMENT Spot Vital Signs n'est pas conçu pour relever des données sur des patients nouveau-nés. Selon la norme AAMI SP10:1992, un nouveau-né est un enfant de moins de 28 jours, s'il est né à terme, (37 semaines de gestation ou plus). Sinon, jusqu'à 44 semaines de gestation.

AVERTISSEMENT Le Welch Allyn Spot Vital Signs n'est pas protégé en cas de défibrillation.

AVERTISSEMENT Le Welch Allyn Spot Vital Signs n'est pas conçu pour un monitorage continu. Ne pas laisser l'appareil sans surveillance lors du relevé de mesures sur un patient.

AVERTISSEMENT Afin d'assurer la sécurité du patient, utiliser uniquement des accessoires et fournitures (à savoir des brassards, des flexibles, des sondes de température, des capteurs de SpO_2, etc.) recommandés ou fournis avec le Spot Vital Signs. L'utilisation d'accessoires non-approuvés avec le Spot Vital Signs peut affecter la sécurité du patient et/ou de l'opérateur.

AVERTISSEMENT Cet appareil n'est pas conçu pour une utilisation en présence d'un mélange anesthésique inflammable avec l'air, l'oxygène ou le protoxyde d'azote. Une explosion pourrait se produire.

AVERTISSEMENT Éviter de comprimer les tubes du brassard ou le tuyau de tensiomètre de tension artérielle du Welch Allyn Spot Vital Signs. La compression des tubes du brassard ou du tuyau de tensiomètre peut entraîner des erreurs du système au niveau du dispositif.

AVERTISSEMENT Il convient de procéder avec soin afin d'empêcher l'eau ou tout autre fluide de pénétrer dans les connecteurs du dispositif. Si cela se produit, les connecteurs doivent être séchés à l'air chaud. Toutes les fonctions d'utilisation doivent ensuite être contrôlées.

AVERTISSEMENT Tout Spot Vital Signs ayant subi une chute ou un dommage doit être vérifié par un technicien qualifié qui s'assurera de son bon fonctionnement avant utilisation. Ne pas utiliser le Welch Allyn Spot Vital Signs en cas de signes d'endommagement. Contacter le Service clientèle de Welch Allyn pour obtenir de l'aide.

AVERTISSEMENT Tous les trois mois, vérifier que la sonde de température, le câble SpO_2 et les accessoires ne s'effilochent pas et qu'ils ne sont endommagés de quelque façon. Remplacer si nécessaire.

AVERTISSEMENT Hormis la batterie, aucune pièce de l'appareil n'est remplaçable par l'utilisateur. Retourner le Spot Vital Signs au centre d'entretien autorisé.

AVERTISSEMENT Le Spot Vital Signs ne doit pas être utilisé sur des patients reliés à des machines cardiaques/pulmonaires.

AVERTISSEMENT Le Spot Vital Signs ne fonctionne pas efficacement sur des patients souffrant de convulsions ou de tremblements.

AVERTISSEMENT Ce dispositif se conforme aux normes courantes exigibles en matière de brouillage électromagnétique et ne devrait ni provoquer d'interférences ni en recevoir de la part d'autres équipements. Par mesure de précaution, éviter d'installer l'appareil à proximité d'autres équipements.

AVERTISSEMENT Ce dispositif n'est pas conçu pour une utilisation manuelle en cours de fonctionnement.

AVERTISSEMENT Welch Allyn recommande de laisser la batterie dans l'appareil, même si ce dernier n'est pas utilisé pendant de longues périodes. En effet, laisser la batterie dans l'appareil ne présente aucun danger.

AVERTISSEMENT Ne pas stériliser en autoclave.

AVERTISSEMENT Welch Allyn n'est pas responsable de l'intégrité de toute installation de montage. Welch Allyn recommande au client de contacter son service d'ingénierie biomédicale ou d'entretien afin de s'assurer de la fiabilité, la sécurité et l'installation professionnelle de tout accessoire de montage.

Avertissements relatifs à la pression artérielle

AVERTISSEMENT Afin d'assurer la précision et la sécurité de la pression artérielle chez l'enfant, le brassard Welch Allyn pour enfant (5200-03), le brassard longue durée mono-pièce Welch Allyn pour enfant en bas-âge (5082-203-3) et le brassard mono-pièce jetable Welch Allyn pour enfant en bas-âge (5082-93-3) sont les plus petits brassards autorisés pour utilisation sur de jeunes enfants et des nourrissons. La circonférence du bras de l'enfant doit se situer dans la plage indiquée sur le brassard.

AVERTISSEMENT Les valeurs de pression artérielle peuvent être imprécises si des brassards et/ou flexibles de pression artérielle autres que ceux fournis par Welch Allyn pour le Spot Vital Signs sont utilisés.

AVERTISSEMENT Les patients souffrant d'arythmies modérées à aiguës peuvent délivrer des mesures de pression artérielle imprécises.

AVERTISSEMENT Lorsque plusieurs valeurs de pression artérielle sont relevées sur le même patient, il est recommandé de contrôler régulièrement l'extrémité et le site du brassard de pression artérielle afin de détecter une ischémie, un purpura et/ou une neuropathie éventuels.

AVERTISSEMENT Ne pas changer le(s) connecteur(s) sur le tuyau du tensiomètre de cet appareil pour un type luer. Les connecteurs de type luer sont couramment utilisés dans des systèmes de perfusion par intraveineuse. L'utilisation de connecteurs luer sur un tuyau de brassard de pression artérielle crée le risque que le tuyau de pression artérielle soit connecté par erreur à une intraveineuse du patient, entraînant l'introduction d'air dans l'appareil circulatoire du patient.

Avertissements relatifs à SpO_2

AVERTISSEMENT N'utiliser Spot Vital Signs avec l'option Masimo ou Nellcor SpO_2 qu'avec les accessoires et capteurs de la marque Masimo ou Nellcor, respectivement. L'utilisation de capteurs ou de câbles erronés ou non-approuvés peut entraîner des performances incorrectes.

AVERTISSEMENT Les rallonges et capteurs SpO_2 sont conçus pour être utilisés uniquement avec les mesures d'oxymétrie pulsée. Ne pas essayer de connecter ces câbles à un PC ou tout autre appareil similaire.

AVERTISSEMENT Avant utilisation, lire soigneusement le mode d'emploi du capteur, y compris tous les avertissements, les précautions et instructions.

AVERTISSEMENT Ne pas utiliser un câble SpO_2 ou de capteur endommagé. Ne pas utiliser un capteur dont les composants optiques sont exposés.

AVERTISSEMENT Un tissu peut être endommagé par une application ou une durée d'utilisation incorrecte d'un capteur SpO_2. Inspecter le site du capteur comme indiqué dans le mode d'emploi du capteur.

AVERTISSEMENT Ne pas utiliser les capteurs en cours d'examen d'imagerie par résonnance magnétique (IRM). Le courant produit peut potentiellement provoquer des brûlures. L'oxymètre de pouls MS board peut affecter l'image de l'IRM et l'appareil d'IRM peut affecter la précision des mesures de l'oxymètre de pouls.

AVERTISSEMENT Certaines conditions environnementales ambiantes, erreurs d'application de capteur et certaines conditions de patients peuvent affecter les valeurs de SpO_2 et le signal de pouls.

AVERTISSEMENT Ne pas immerger les câbles patient ou capteur dans de l'eau, des solvants ou des solutions de nettoyage (les capteurs et les connexions ne sont pas étanches). Ne pas utiliser de rayonnement, de vapeur ou d'oxyde d'éthylène pour la stérilisation.

AVERTISSEMENT Ne pas utiliser le câble SpO_2 ou le câble d'alimentation pour soulever l'unité. En effet, ces deux câbles sont susceptibles de se déconnecter de l'appareil, entraînant la chute de l'appareil sur le patient.

AVERTISSEMENT Le SpO_2 du Welch Allyn Spot Vital signs n'est pas conçu pour une utilisation comme moniteur d'apnée.

AVERTISSEMENT Considérer le SpO_2 comme un dispositif d'avertissement précoce. Si une tendance à la désoxygénation du patient est indiquée, utiliser des instruments de laboratoire pour analyser des prélèvements sanguins afin de comprendre complètement l'état du patient.

Avertissements relatifs à la température

AVERTISSEMENT Les embouts de sonde jetables à usage unique, disponibles auprès de Welch Allyn, limitent les contaminations entre patients. Il est spécialement déconseillé d'utiliser tout autre embout de sonde ou de ne pas utiliser d'embout. En effet, cela peut générer des erreurs de température.

AVERTISSEMENT N'utiliser que des sondes orales (bleues) pour le relevé de températures orales et axillaires. N'utiliser que des sondes rectales (rouges) pour le relevé de températures rectales. L'utilisation de la mauvaise sonde peut produire des erreurs de température.

AVERTISSEMENT Ne pas laisser l'extrémité de la sonde de température entrer en contact avec une source de chaleur (par ex. les mains ou les doigts) avant de procéder à un relevé de température. Si cela se produit, jeter l'embout de la sonde et reprendre la détermination de la température.

AVERTISSEMENT Un monitorage continu longue durée de trois à cinq minutes n'est pas recommandé, quel que soit le mode.

Avertissements relatifs au port de communication infrarouge

AVERTISSEMENT Le Welch Allyn Spot Vital Signs contient un port de communication infrarouge pour les communications isolées avec des périphériques externes. Ce port se trouve sur le côté de l'appareil pour empêcher tout contact visuel direct continu lors de la consultation de l'affichage. À titre de précaution, ne pas regarder directement le port infrarouge en cours de fonctionnement.

Précautions générales

Dans ce manuel, Attention identifie les conditions ou pratiques qui, si elles ne sont pas corrigées ou arrêtées immédiatement, risquent de provoquer des pertes de données, un endommagement ou une défaillance du matériel.

Attention Si la précision de toute mesure est mise en question, vérifier le(s) signe(s) vital (vitaux) du patient en employant une autre méthode, puis s'assurer que l'appareil fonctionne correctement.

Attention S'assurer que l'appareil est situé sur une surface sûre ou utiliser un des accessoires de montage optionnels.

Attention Ne pas placer de fluides sur l'appareil.

Précautions relatives à la pression artérielle

Attention Veiller à minimiser le mouvement de l'extrémité et du brassard de pression artérielle en cours de détermination de la pression artérielle.

Attention Si le brassard de tensiomètre n'est pas au niveau du coeur, la différence de valeur due à l'effet hydrostatique doit être notée. La valeur de 1,80 mmHg doit être ajoutée à la valeur affichée pour chaque pouce (2,5 cm) au-dessus du niveau du coeur. La valeur de 1,80 mmHg doit être retirée à la valeur affichée pour chaque pouce (2,5 cm) en dessous du niveau du cœur.

Attention Il est essentiel que le brassard de tensiomètre soit à la taille et l'emplacement adéquats pour assurer la précision de la détermination de la pression artérielle. Voir "Tableau de détermination de la taille de brassard de tensiomètre" on page 17 pour obtenir des informations sur la taille du brassard de pression artérielle.

Attention Lors de la mesure de la pression artérielle sur des enfants de moins de 3 ans, il est recommandé de définir le réglage de la pression (pression de gonflage initiale) sur une valeur inférieure ou égale à 160 mmHg.

Précautions relatives à SpO_2

Attention L'oxymètre de pouls est étalonné pour déterminer le pourcentage de saturation en oxygène du sang artériel de l'hémoglobine fonctionnelle. Des niveaux importants d'hémoglobine dysfonctionnelle comme la carboxyhémoglobine ou méthémoglobine peuvent affecter la précision de la mesure.

Attention Certaines conditions physiologiques, interventions médicales ou substances externes sont susceptibles d'interférer avec les fonctions de détection et de mesure de l'oxymètre de pouls, par exemple les hémoglobines dysfonctionnelles, les colorants artériels, les conditions de faible perfusion et les pigments foncés, ainsi que les agents de coloration appliqués par voie externe, tels que le vernis à ongle, les teintures ou les crèmes pigmentées.

Attention Certains capteurs peuvent s'avérer inadéquats pour un patient en particulier. S'il n'est pas possible d'observer au moins 15 secondes d'impulsions de perfusion pour un capteur donné, modifier l'emplacement du capteur ou le type de capteur pour la perfusion afin de reprendre l'opération.

Attention Lors du choix d'un capteur, prendre en considération le poids du patient et son niveau d'activité, l'adéquation de la perfusion, les sites de capteurs disponibles, le besoin de stérilité et la durée prévue du monitorage.

Précautions relatives à la température

Attention Le Welch Allyn Spot Vital Signs est approuvé par la FDA pour mesurer la température axillaire en mode normal pour les enfants de moins de 4 ans. Les températures axillaires du mode normal peuvent ne pas être précises sur des enfants plus âgés ou des adultes. *LE WELCH ALLYN SPOT VITAL SIGNS N'EST PAS CONÇU POUR UNE UTILISATION SUR DES NOUVEAU-NÉS.*

2 Controls, Indicators, and Connections

In this section, all drawing and text are representative of the Spot Vital Signs with all available options. Your device may not include all functions, depending on the options purchased.

Unpacking Checklist

Unpack the Welch Allyn Spot Vital Signs and applicable accessories, identify each item with the following checklist and inspect for missing items. Retain the shipping materials in the event of shipping damage or for return, if necessary, to Welch Allyn for repair or warranty service. All Spot Vital Signs include the following components:

Spot Vital Signs Device. This device automatically measures and displays blood pressure and pulse rate. Options include thermometry and pulse oximetry.

Directions for Use Manual. Read this manual thoroughly before using Spot Vital Signs. Save this manual for reference.

Warranty Card. This card validates the Spot Vital Signs warranty. Fill out the warranty card and mail it today.

Blood Pressure Cuff. Latex free blood pressure cuff with connectors. Other size cuffs are available separately.

Blood Pressure Hose. Latex-free pressure hose with connectors to attach various sizes of blood pressure cuffs to the Spot Vital Signs.

AC Power Transformer and Cord Assembly. Provides power to the Spot Vital Signs and charges the internal battery.

Quick Reference/Error Code Card. Attach this quick operating and error code guide to the device handle, mobile stand, or wall mount.

Possible Attachments

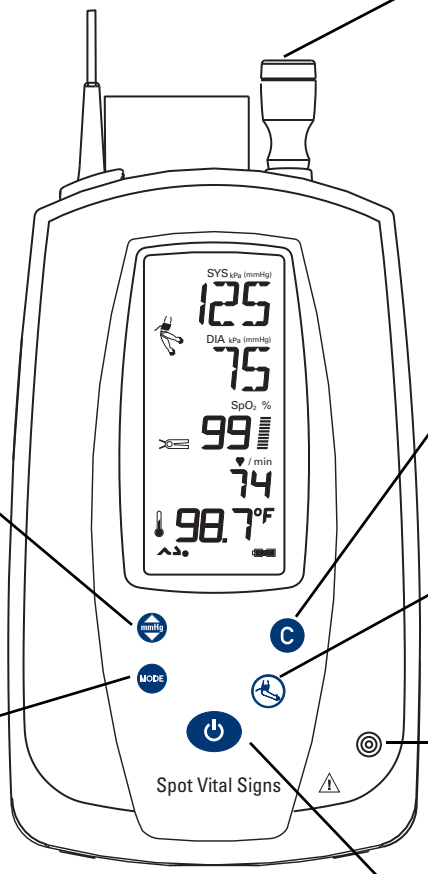
Spot Vital Signs may include the following items based on the model and accessories purchased:

SureTemp Temperature Probe and Covers. One oral temperature probe (blue cap) and one box of 25 single-use, disposable probe covers.

Pulse Oximetry (SpO_2). The finger clip SpO_2 sensor and extension cable are for use with adult and pediatric patients. Other sensors are available separately.

Note Report any signs of shipping damage to the carrier. If an item is missing or damaged, contact the Welch Allyn Service Center near you.

Front Panel Functions



Thermometer Eject Button: push to remove used temperature probe cover.

Next Patient/Clear/Cancel Button:
- active display: clears the display.
- in Standby Mode: recalls the last patient information. Pressing a second time clears the screen.
- cancels an active blood pressure measurement and deflates the cuff.

Pressure Preset Button: pressing this button allows the user to change the factory inflation default for one reading.

Blood Pressure Start/Stop Button: initiates a new blood pressure cycle. Pressing again cancels an active blood pressure measurement and deflates the cuff.

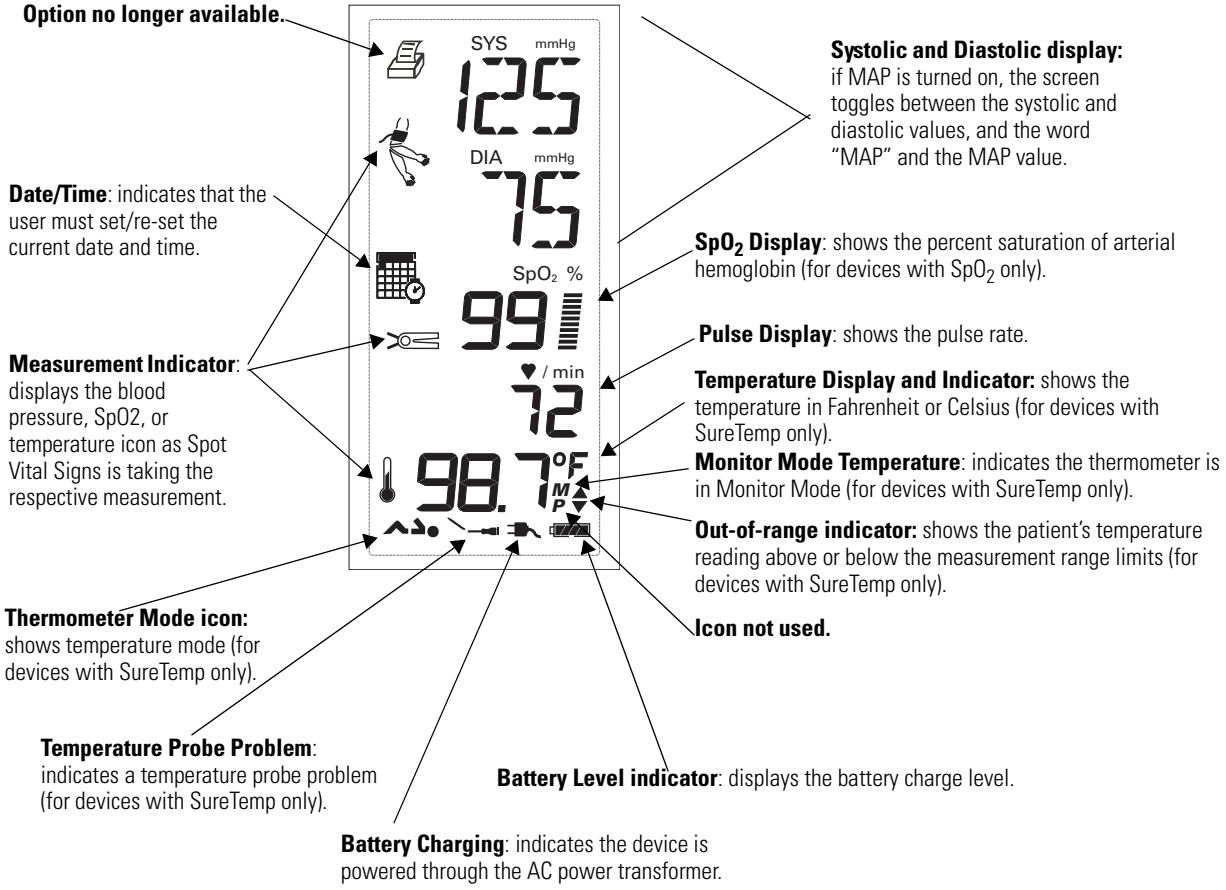
Mode Button:
- holding for 2 seconds while the display is active turns off/on the backlight.
- in Standby Mode, recalls the last patient information.
- with the temperature probe removed from the probe holder, switches the temperature from Oral to Axillary Mode.

Pressure Hose Connector: port for blood pressure hose.

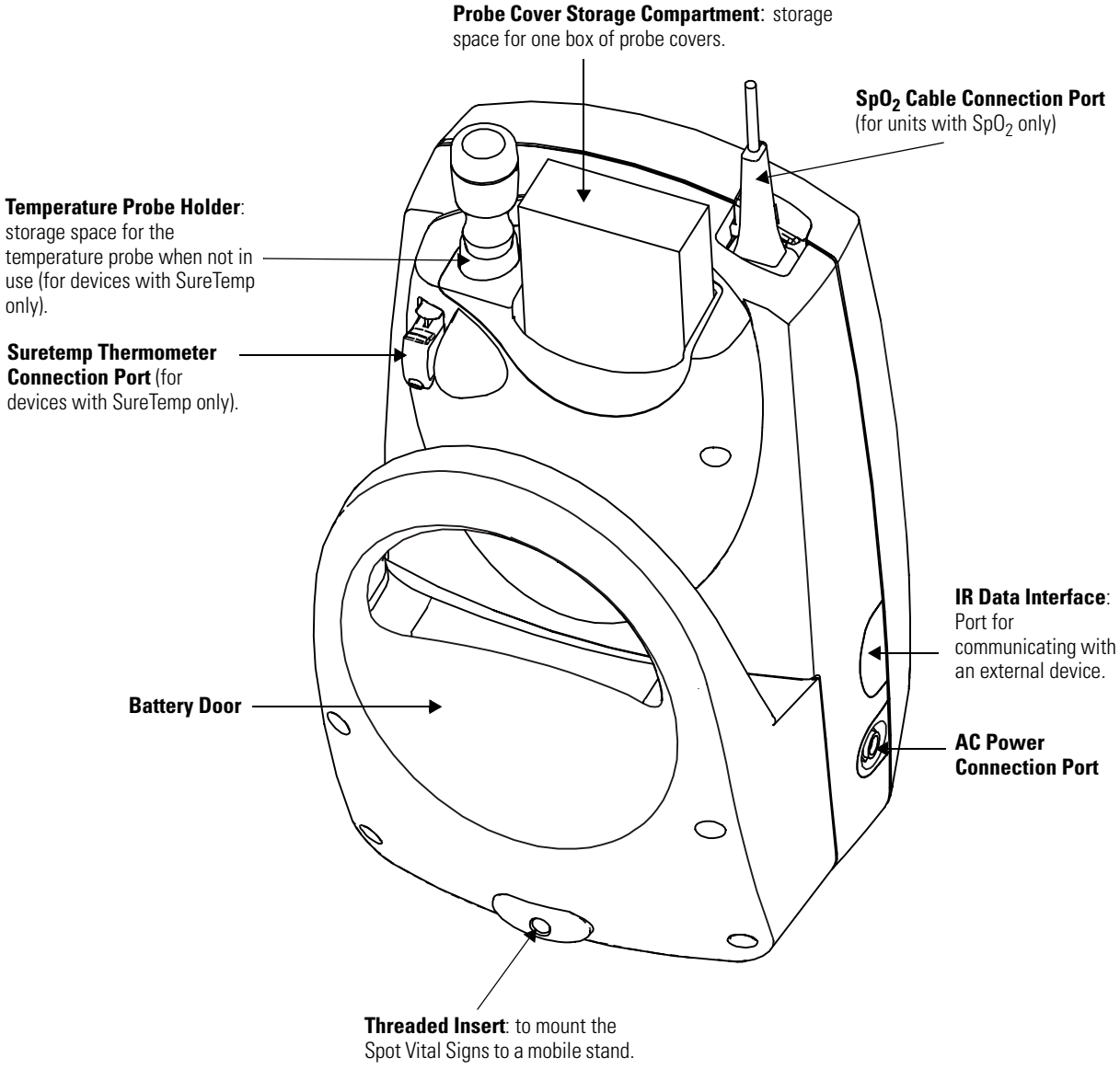
Power Button: controls power to the device.

LCD (Liquid Crystal Display)

The LCD may indicate any of the following: systolic blood pressure (mmHg or kPa), diastolic blood pressure (mmHg or kPa), temperature (°F or °C), thermometer mode, pulse rate, pulse signal level, SpO_2, MAP (mmHg or kPa), and battery charge level.


Option no longer available.
SYS mmHg
125
DIA mmHg
75
SpO₂ %
99
/ min
72
98.7°F
M
P
Systolic and Diastolic display: if MAP is turned on, the screen toggles between the systolic and diastolic values, and the word "MAP" and the MAP value.
Date/Time: indicates that the user must set/re-set the current date and time.
SpO2 Display: shows the percent saturation of arterial hemoglobin (for devices with SpO2 only).
Pulse Display: shows the pulse rate.
Measurement Indicator: displays the blood pressure, SpO2, or temperature icon as Spot Vital Signs is taking the respective measurement.
Temperature Display and Indicator: shows the temperature in Fahrenheit or Celsius (for devices with SureTemp only).
Monitor Mode Temperature: indicates the thermometer is in Monitor Mode (for devices with SureTemp only).
Out-of-range indicator: shows the patient's temperature reading above or below the measurement range limits (for devices with SureTemp only).
Icon not used.
Thermometer Mode icon: shows temperature mode (for devices with SureTemp only).
Temperature Probe Problem: indicates a temperature probe problem (for devices with SureTemp only).
Battery Level indicator: displays the battery charge level.
Battery Charging: indicates the device is powered through the AC power transformer.

Top, Side, and Rear Panel Connections


Probe Cover Storage Compartment: storage space for one box of probe covers.
SpO_2 Cable Connection Port (for units with SpO_2 only)
Temperature Probe Holder: storage space for the temperature probe when not in use (for devices with SureTemp only).
Suretemp Thermometer Connection Port (for devices with SureTemp only).
IR Data Interface: Port for communicating with an external device.
Battery Door
AC Power Connection Port
Threaded Insert: to mount the Spot Vital Signs to a mobile stand.

3 Internal Configuration

You can change several device operating parameters in the Internal Configuration Mode. When changed, these settings become the default power-up settings. You will also see non-changeable device configurations for technical service purposes.

To enter the Internal Configuration Mode:

1. Turn the Spot Vital Signs off.
2. Press and hold the **Power** and **Blood Pressure Start/Stop** buttons. The device enters the Internal Configuration Mode and displays the software version.
3. Press the **Mode** button to cycle through the Internal Configuration menu until you see the menu option displayed on the screen.
4. Use the **Next Patient/Clear/Cancel** or **Blood Pressure Start/Stop** buttons to change the default setting.
5. Press the **Mode** button once to save the change and press the **Power** button to exit the Internal Configuration Mode.

Table 2. Configuration Menu Options

Setting	Description
Blood Pressure Calibration Displays “Cal”	Prepares the Spot Vital Signs for calibration. Only qualified personnel should verify the Spot Vital Signs blood pressure calibration. For more details, see “Checking the Blood Pressure Calibration” on page 26.
Inflation Pressure Preset Level Displays “PrP”	120, 140, 160, 180, 200, 240, 280 mmHg. Factory default is 160 mmHg.
Pressure Preset Level Displays “PrP“	On or off. Disables or enables the front panel Pressure Preset button.
Backlight Displays “BLT“	On or off.
Mean Arterial Pressure Displays “MAP”	On or off.
Date/Time	Changes or updates the actual date and time.
Temperature Scale Displays “TMP MOD”	Fahrenheit (°F) or Celsius (°C) Normal Mode / Fahrenheit (°F) or Celsius (°C) Monitor Mode
Blood Pressure Units Displays “BP”	mmHg or kPa.
Battery Readings Displays “BAT”	Displays the total battery voltage.
Battery Life Displays “LFE”	Total number unit measurements. Displayed information only; operator cannot change.

4 Setup

Blood Pressure Hose and Cuff Connections

Have available the Spot Vital Signs, blood pressure cuff, and blood pressure hose.

1. Inspect the pressure hose; note that one end has a connector fitting and the other end does not. Attach the end without the connector fitting to the pressure hose connector (see page 16). Verify that the pressure hose is completely inserted over the connector and that the fit is snug.
2. Join the other end of the pressure hose to the blood pressure cuff pneumatic tubing. Twist the connectors together until finger-tight. ***DO NOT OVERTIGHTEN***.

Temperature Probe Connection

The Welch Allyn Spot Vital Signs is available with two probes — one for oral/axillary temperatures (blue cap), and one for rectal temperatures (red cap). The rectal probe is an accessory item that is ordered separately.

Press down on the tab on top of the connector and insert the connector into the temperature probe connector port on the back of the Spot Vital Signs. The probe connector only fits into Spot Vital Signs one way. Verify the connector clicks into place. Insert the temperature probe into the probe holder on the top of the Spot Vital Signs.

To remove the temperature probe, press down on the connector tab and lift out.

SpO_2 Sensor Connection

Spot Vital Signs is available with a wide variety of SpO_2 sensors and ships with a reusable finger sensor and extension cable. All other sensors are accessory items that are sold separately.

1. Align the shape and pin configuration of the extension cable connector to the SpO_2 cable connection port on the top side of the Spot Vital Signs device.
2. Push the connector firmly into the SpO_2 cable connection port.
3. Align the opposite end of the extension cable to the sensor cable connector and firmly push them together.

Note Use only Masimo or Nellcor SpO_2 sensors and accessories with the Spot Vital Signs with Masimo or Nellcor configurations, respectively.

Quick Reference/Error Code Card

The Quick Reference/Error Code Card should be attached either to the Spot Vital Signs handle, the Mobile Stand, or the Wall Mount.

AC Power Connection

Use the Spot Vital Signs with AC or battery power (after charging the battery).

1. Insert the round transformer connector into the AC power connection port on the left of the Spot Vital Signs (see page 18).
2. Insert the line cord into the line connector on the transformer then plug the power cord on the transformer into the AC main power source to charge the battery.

Charging the Battery

CHARGE THE BATTERY FOR SIXTEEN (16) HOURS PRIOR TO INITIAL USE.

Attach the AC power transformer to the Spot Vital Signs then plug the transformer into the AC main power source.

While charging, the charger icon remains on and the battery icon segments continuously sequence. When the battery is fully charged, all battery icon segments display.

As the battery voltage level drops the segments turn off from left to right. If the Spot Vital Signs is not plugged in to charge when the second last segment is turned off the Spot Vital Signs issues a warning beep. As the voltage level drops to compromise measurements an error beep is heard and all other display fields turn off. Spot Vital Signs beeps at increasingly frequent intervals until it finally powers itself off.

If not used for extended periods of time then recharge the battery.

Standby Mode

When the device is powered up, but has not been used for 2 minutes, it goes into Standby Mode. "Z Z Z" appears across the top of the display with no backlight. Standby Mode conserves battery power.

To bring the Spot Vital Signs out of Standby Mode, press the **Mode** or **Pressure Preset** button or begin a patient measurement.

5 Blood Pressure

Caution When measuring blood pressure on children younger than age 3, it is recommended that the Pressure Preset (initial inflation pressure) be set at 160 mmHg or lower.

Selecting the Blood Pressure Cuff

Note A durable blood pressure cuff is included with your Spot Vital Signs. A full range of blood pressure cuff sizes are available as accessory items.

Careful sizing of the blood pressure cuff is important to the accuracy of blood pressure readings. If the blood pressure cuff is too small, you may have false high readings. If the blood pressure cuff is too large, you may have false low readings. Please refer to the range markings on the blood pressure cuff for correct blood pressure cuff sizing. When there is an area of overlap whereby you could use a smaller or larger blood pressure cuff, it is strongly recommended that you use the larger size blood pressure cuff.

Determining Blood Pressure Cuff Size with the Markings

Wrap the blood pressure cuff around the patient's upper arm and visually check it. The blood pressure cuff is marked with a distinct white edge and two divisions that indicate "range." When the blood pressure cuff is properly fit, the edge meets the blood pressure cuff at some point within the range.

Chart for Determining Blood Pressure Cuff Size

You can also determine blood pressure cuff size by measuring the patient's arm circumference midway between the elbow and shoulder, then use the chart below to select the correct blood pressure cuff.

Cuff Size	Reusable Two-Piece Cuff (1 per pack)	Maximum Range (cm)	Maximum Range (in)
Child	5200-03	20.8	8.2
Adult	5200-01	31.5	12.4
Large Adult	5200-02	38.4	15.1
Thigh	5200-10	47.4	18.7

Durable One-Piece Cuff (Single Unit)	Disposable One-Piece Cuffs (5 pack)	Cuff Size	Minimum (cm)	Maximum (cm)	Minimum (inches)	Maximum (inches)
5082-203-3	5082-93-3	Small Child	12.4	16.8	4.9	6.6
5082-204-3	5082-94-3	Child	15.8	21.3	6.2	8.4
5082-205-3	5082-95-3	Small Adult	20.0	27.0	7.9	10.6
5082-206-3	5082-96-3	Adult	25.3	34.3	10.0	13.5
5082-207-3	5082-97-3	Large Adult	32.1	43.4	12.6	17.1
5082-208-3	5082-98-3	Thigh	40.7	55.0	16.0	21.7

THE WELCH ALLYN SPOT VITAL SIGNS IS NOT INTENDED FOR USE ON NEONATAL PATIENTS.

To ensure pediatric blood pressure accuracy and safety, the Welch Allyn Child Print Cuff (5200-03), the Welch Allyn Small Child Durable One-Piece Cuff (5082-203-3), and the Welch Allyn Small Child Disposable One-Piece Cuff (5082-93-3) are the smallest cuffs allowed for use with young children and infants. The circumference of the child's arm must fit within the range markings on the blood pressure cuff.

To position the blood pressure cuff:

The preferred blood pressure measurement site for adults and children is the upper arm. Keep the patient's arm relaxed and motion-free during measurement(s).

WARNING Do not place the blood pressure cuff on any extremity that is used for intravenous infusions or any area where circulation is compromised.

WARNING Do not change the connector(s) on the blood pressure cuff tubing of this device to luer type. Luer type connectors are commonly used in intravenous infusion systems. Using the luer connectors on blood pressure cuff tubing creates the risk that the blood pressure tubing could be mistakenly connected to a patient's intravenous line, resulting in the introduction of air into the patient's circulatory system.

Note Blood pressure cuff inflation during an SpO_2 measurement may cause inaccurate SpO_2 results when used on the same extremity.

Wrap the blood pressure cuff snugly with room between the blood pressure cuff and the arm for no more than two fingers. Excessive tightness may cause venous congestion and discoloration of the limb. Possible error may occur if the blood pressure cuff is wrapped too loosely, preventing proper inflation.

Place the blood pressure cuff on a bare arm; clothing interferes with measurement accuracy. Verify that the cuff artery marker is placed over the brachial artery. Ensure that the hose is not twisted, kinked, or compressed, as this may cause measurement errors.

To set the pressure preset level (one time only):

1. Press and hold the **Pressure Preset** button for half a second. Spot Vital Signs displays "PrP" (pressure preset) in the SYS and the inflation pressure in the DIA displays, respectively.
2. Push the **Pressure Preset** button. The blood pressure cuff inflation pressure decreases in 20 mmHg increments beginning at 160 mmHg (160 -> 140, 120, 200, 180, 160).

   To return to the normal operating mode, push the **Next Patient/Clear/Cancel** button or wait 3 seconds.

   The inflation pressure resets to the default pressure setting after completing one blood pressure cycle. The factory default is 160 mmHg.

There is a disable feature in the Internal Configuration Mode that allows the facility to disable this button, see page 19.

To initiate a blood pressure measurement:

1. Ensure that the blood pressure cuff is properly sized and wrapped around the patient's upper arm (or alternate site, as necessary).
2. With the device powered on, press the **Blood Pressure Start/Stop** button.The Spot Vital Signs inflates the blood pressure cuff to the appropriate pressure and displays the pressure as the blood pressure measurement is in process.

   Pressing the **Blood Pressure Start/Stop** or the **Next Patient/Clear/Cancel** button at any time during a blood pressure determination cancels the measurement and rapidly deflates the blood pressure cuff.

   When the measurement cycle is complete the Spot Vital Signs beeps once and displays the systolic, diastolic, and pulse rate* measurements for two minutes (unless another measurement is active). If the MAP is turned on then the Spot Vital Signs toggles between the blood pressure reading and the MAP value.

   If Spot Vital Signs cannot take a successful blood pressure measurement it beeps twice and displays a "C" error code unless the measurement was purposely stopped.

* Pulse rate, as determined from the blood pressure measurement method, is displayed with the blood pressure reading only if the SpO_2 option is not in use. If the SpO_2 function is in use, all pulse rate determinations are a result of the SpO_2 measurement method.

Reviewing Information from the Last Cycle

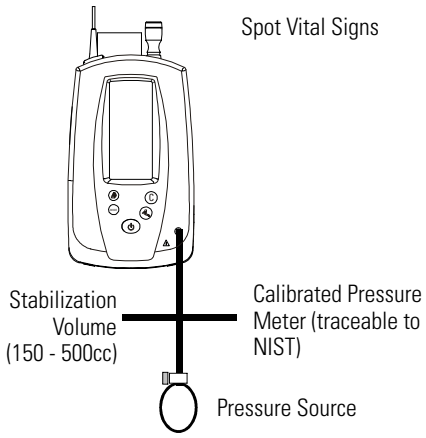
The Spot Vital Signs holds the last patient measurement cycle in memory. The information is held in memory until the unit is turned off or you initiate the next patient's measurement. If the display is blank, press the **Mode** button to review data from the last measurement cycle.

Checking the Blood Pressure Calibration

The Welch Allyn Spot Vital Signs is manufactured to the highest industry standards for quality and accuracy. The device is manufactured using calibrated pressure standards traceable to NIST (National Institute of Standards and Technology). Welch Allyn recommends that blood pressure calibration for the Spot Vital Signs is checked on an annual basis using the following procedure.

Put the Spot Vital Signs into its blood pressure calibration check mode. In this mode, the device continuously displays the measured pressure and closes the pressure release valve.

1. Enter the internal configuration mode (see "Internal Configuration" on page 19).
2. Press the **Blood Pressure Start/Stop** button to close the device's internal valve to apply an external pressure.
3. Connect the Spot Vital Signs as shown to a calibrated pressure meter (verify certificate is traceable to the National Institute of Standards and Technology. **The pressure meter testing the Spot Vital Signs must have an accuracy of better than ±3 mmHg.** Use a fixed volume or a blood pressure cuff wrapped around a cylinder for the stabilization volume.



4. Pressurize the Spot Vital Signs to slightly above 250 mmHg. Bleed the pressure to approximately 250 mmHg. Clamp and record the pressure reading and the measurement standard. Repeat this step for 150 and 50 mmHg (approximate).
5. Calculate the difference between the readings. Subtract the rated accuracy of the pressure measurement standard from the ±3 mmHg rated accuracy of Spot Vital Signs. This is the **pass/fail criteria** to determine if the device is within calibration or not. If the differences between Spot Vital Signs and the pressure measurement standard are within the pass/fail criteria at all specified pressures, then the device is within calibration.

If the Spot Vital Signs needs re-calibration the procedures are included in the Spot Vital Signs Service Manual. Alternatively, send the device back to Welch Allyn for calibration by contacting Technical Service.

Note The pass/fail criteria for the blood pressure calibration check depends upon the accuracy of the pressure measurement standard used. For example:

- If the pressure measurement standard used is rated with an accuracy of ±0.1 mmHg, the pass/fail criteria is ±2.9 mmHg in order to guarantee that the instrument under test is within ±3 mmHg of NIST.
- If the pressure measurement standard used is rated with an accuracy of ±1.0 mmHg, the pass/fail criteria is ±2.0 mmHg in order to guarantee that the instrument under test is within ±3 mmHg of NIST.

Welch Allyn recommends using a pressure meter that is as accurate as possible when performing calibration checks. Welch Allyn offers two different pressure measurement standards for use:

- Setra Pressure Meter, calibrated accuracy of ±0.1 mmHg (part no. 2270-01)
- Netech Pressure Meter, calibrated accuracy of ±1.0 mmHg (part no. 200-2000IN)

Use of other pressure measurement standards is acceptable, provided they have an accuracy of better than ±3 mmHg, are traceable to NIST, and have a current calibration.

Note Do not take more than 3 minutes to take the readings, as the Spot Vital Signs will open its pressure relief valve as a safety feature. If this occurs, turn the device off and start over.

The Spot Vital Signs has the option to measure pressure in kPa units. If the device is set to kPa instead of mmHg, temporarily set the device to mmHg units or convert all pressures to kPa units.

6 Temperature

WARNING Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.

Selecting Temperature Operation Mode

When configured with the temperature option, the Welch Allyn Spot Vital Signs takes a temperature in either Normal or Monitor Mode.

In the Normal Mode, the thermometer "predicts" body temperature in approximately 4 seconds for oral temperatures, 10 seconds for axillary temperatures, and 15 seconds for rectal temperatures.

Monitor Mode is normally used when difficult situations prevent taking an accurate temperature in the Normal Mode. In Monitor Mode, maintain probe contact with the tissue for at least 3 minutes for accurate oral/rectal temperature measurement, and 5 minutes for accurate axillary temperature measurement.

The default setting for the Spot Vital Signs thermometer is Normal Mode.

Temperature Measurement Range Indicators

The following display appears when temperatures are outside of the measurement range of the device:

Condition	Temperature	Display	Audible Notification
Temperature is outside of high measurement range of the device	Fahrenheit Celsius	109.4° ⇑ 43° ⇑	No
Temperature is outside of low measurement range of the device	Fahrenheit Celsius	86° ⇓ 30° ⇓	No

Normal Mode

Patient actions may interfere with accurate oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum or mints, brushing teeth, smoking, or performing strenuous activity may affect oral temperature readings for up to 20 minutes after activity has ended.

Probe contact with electrodes or bandages, poor tissue contact, taking an axillary temperature over clothing, or prolonged exposure of axilla to ambient air can cause inaccurate axillary temperature readings.

WARNING To ensure optimal accuracy, always confirm that the correct mode is selected.

WARNING Use only Welch Allyn probe covers. Using other manufacturers' probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy.

To take a temperature in oral or axillary mode:

WARNING Do not take an axillary temperature over the patient's clothing. Direct contact between the patient's skin and the probe is required.

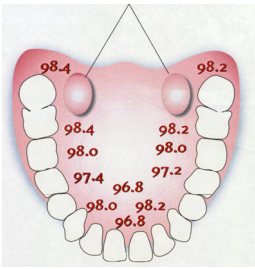
Caution Use the temperature probe with the blue cap to obtain accurate oral or axillary temperatures.

Note Normal Mode axillary temperatures are FDA cleared for children under the age of four. THE WELCH ALLYN SPOT VITAL SIGNS IS NOT INTENDED FOR USE ON NEONATAL PATIENTS.

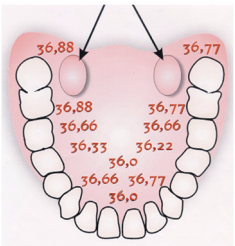
1. Verify that the correct probe (blue cap) is installed.
2. Hold the probe handle with your thumb and two fingers on the sides of the probe handle and withdraw the probe.
3. Verify the desired temperature mode is in the temperature display area and the desired temperature mode icon is flashing.

   If the desired mode is not selected, press the **Mode** button until the LCD displays "OrL" or "ALy".
4. Insert the probe into a probe cover and press the probe handle down firmly. The probe handle moves slightly to engage the probe cover.
5. Quickly put the probe in place.
   a. For oral temperatures, place the probe tip under the patient's tongue on either side of the mouth to reach the sublingual pocket and ask the patient to close his/her lips.

SUBLINGUAL POCKET



SUBLINGUAL POCKET



b. For axillary temperatures, lift the patient's arm so that the entire axilla is easily seen and place the probe as high as possible in the axilla. Do not allow the probe tip to come into contact with the patient until the probe is placed in the measurement site. Any prior contact between the probe tip and the tissue with another material may cause inaccurate readings. Verify that axillary tissue completely surrounds the probe tip and place the arm snugly at the patient's side.

6. Firmly hold the probe in place and keep the tip of the probe in contact with the tissue throughout the measurement process. During the measurement process, the temperature display area displays rotating "walking" segments.

   Spot Vital Signs beeps once after reaching the final temperature. The temperature display area displays the patient temperature. Spot Vital Signs displays the current temperature for two minutes after the probe is placed back in the holder. The display then goes blank (unless another measurement is active).

   If Spot Vital Signs displays a probe position icon during the temperature determination, the temperature display alternates between the final predicted temperature and the letter "P".

   To switch to Monitor Mode, leave the probe in place after obtaining a reading and press the **Mode** button once. The temperature display shows an "M" to indicate Monitor Mode. Once in Monitor Mode proceed to Step 5 on page 33.

7. Remove the probe after the temperature measurement is complete and firmly press the ejection button on the top of the probe to release the probe cover.

8. Return the probe to Spot Vital Signs.

To take a temperature in Rectal Mode:

WARNING Incorrect insertion of probe can cause bowel perforation.

WARNING Washing hands greatly reduces the risk of cross-contamination and nosocomial infection.

Caution To obtain accurate rectal temperatures, use the temperature probe with the red ejection button.

1. Verify that the rectal probe (red cap) is installed. Spot Vital Signs only operates in Rectal Mode if the red rectal probe is installed.

2. Hold the probe handle with your thumb and two fingers on the sides of the probe handle and withdraw the probe from Spot Vital Signs.

3. Verify the Spot Vital Signs temperature display shows "rEC" to indicate a rectal probe is in use.

4. Insert the probe into a probe cover and press the probe handle down firmly. The probe handle moves slightly to engage the probe cover.

5. Separate the patient's buttocks with one hand. Use the other hand to gently insert the probe only 5/8 in. (1.5 cm) inside the rectum (less for infants and children). The use of a lubricant is optional.

6. Tilt the probe so that the tip is in contact with tissue. Continue to separate the buttocks and hold the probe in place throughout the measurement process. During the measurement process, the temperature display area displays rotating "walking" segments.

Spot Vital Signs beeps once after reaching the final temperature. The temperature display area displays the patient temperature. Spot Vital Signs displays the current temperature for two minutes after the probe is placed back in the holder. The display then goes blank (unless another measurement is active).

If Spot Vital Signs displays a probe position icon during the temperature determination, the temperature display alternates between the final predicted temperature and the letter "P".

To switch to Monitor Mode after obtaining a reading, leave the probe in place after obtaining a reading and press the Mode button once. The temperature display shows an "M" to indicate Monitor Mode. Once in Monitor Mode proceed to Step 5 on page 33.

7. Remove the probe after the temperature measurement is complete and firmly press the ejection button on the top of the probe to release the probe cover.
8. Return the probe to Spot Vital Signs and wash your hands.

Monitor Mode

Monitor Mode displays the temperature of the probe as long as the probe remains in place at the measurement site and remains within the operating patient temperature range. The patient's temperature will reach final equilibrium in approximately three minutes in the oral and rectal sites and five minutes in the axillary site.

WARNING Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.

Note To switch to Monitor Mode without taking a predictive temperature, remove the probe from the holder, attach a new probe cover, and wait one minute. Do not place the probe in the patient's mouth, underarm, or rectum. After one minute, the thermometer switches to Monitor Mode and an "M" shows in the temperature display. Continue to take the patient's temperature.

To take a temperature in Monitor Mode:

1. Verify that the correct probe (oral/axillary = blue cap or rectal = red cap) is installed.
2. Hold the probe handle with your thumb and two fingers on the sides of the probe handle and withdraw the probe from Spot Vital Signs.
3. Insert the probe into a probe cover and press the probe handle down firmly. The probe handle moves slightly to engage the probe cover.
4. Take the patient's temperature using the Normal Mode as previously described. Leave the probe in place after Spot Vital Signs beeps once and displays the temperature. Press the **Mode** button once. An "M" appears on the display to indicate Monitor Mode.
5. Hold the thermometer in place for a total of three minutes for oral and rectal mode or five minutes for axillary mode. The thermometer will not beep to indicate a final temperature.
6. Record the temperature before removing the probe from the site; the monitored temperature does not remain on the display once the probe is removed from the site and is not stored in memory for recall.
7. Remove the probe from the patient and firmly press the ejection button on the top of the probe to release the probe cover.
8. Return the probe to the Spot Vital Signs to reset the thermometer to Normal Mode.

7 Pulse Oximetry (SpO_2)

Factors that may degrade the performance of the pulse oximeter:

- Excessive ambient light
- Anemia or low hemoglobin concentrations
- Moisture in the sensor
- Incorrect sensor for patient
- Venous pulsations
- Sensor not at heart level
- Fingernail polish (if finger sensor is used)
- Cardiovascular dyes
- Electrosurgical interference
- Excessive motion
- Arterial catheters, blood pressure, and infusion lines, etc.
- Improperly attached sensor
- Poor patient perfusion

WARNING Tissue damage can be caused by incorrect application or duration of use of an SpO_2 sensor. Inspect the sensor site as directed in the sensor Directions for Use.

WARNING Do not use a damaged sensor or pulse oximetry cable or a sensor with exposed optical components.

To take an SpO_2 measurement:

If blood pressure measurement is occurring simultaneously, place the finger sensor on the limb opposite the one with the blood pressure cuff.

1. Insert the patient's finger completely into the sensor; the thumb is specifically not recommended for use with the finger clip sensor.

   The pulse signal bar graph illuminates, indicating the patient's pulse at the sensor site. The sensor takes approximately 10 seconds to determine the initial SpO_2% value and pulse rate. When the initial values are determined, they are shown in the SpO_2 display and the pulse rate display, respectively. If the accuracy of any measurement does not seem reasonable, first use an alternate means to check the patient's vital signs and then check the Spot Vital Signs for proper functioning.

   Spot Vital Signs measures a patient's SpO_2 for up to 10 minutes. After 10 minutes, Spot Vital Signs displays a C9 error code and beeps twice. This error code means that the use has exceeded the 10-minute time limit.To clear the error code, disconnect the sensor from Spot Vital Signs and then re-attach it or press the **Next Patient/Clear/ Cancel** button.

2. Check sensor sites periodically to assess circulation, sensor positioning, and skin sensitivity.

3. Remove the sensor from the patient. The device continues to display the last SpO_2 reading.

8 Error Indications and Interpretation

The following table of conditions and error codes provides a quick reference of the descriptions and probable causes of error codes.

To clear the error code:

Power the Spot Vital Signs off, wait five seconds, and power on. If the error code reappears then power the Spot Vital Signs off and disconnect the battery for five minutes. Reconnect the battery and power on. If the error code continues to reappear, call Welch Allyn for a Service Notification Number (see "Technical Assistance" on page 56).

Press the Blood Pressure Start/Stop button to reset flashing patient alarm conditions.

Error Codes

Table 1. General

Code	Description	Corrective Action
E11	Internal safety violation	Check patient, contact Technical Service.
C12	Ambient temperature out of range	Adjust ambient temperature or device location.
C13	Battery failure	Use wall transformer.
E0.0 - E9.9	Temperature module malfunction	Contact Technical Service.
E42	Internal communications error	Disconnect the battery and wait 5 minutes. Reconnect the battery and then set the date and time, see "Blood Pressure Hose and Cuff Connections" on page 21.
E20 - E50	General internal malfunction	Contact Technical Service.

Table 2. Blood Pressure

Code	Description	Corrective Action
C02	Auto-zero failure	Check for air obstruction, limit patient movement.
C03	Inflation too rapid	Check for kinked blood pressure cuff tubing, pressure hose, or other air obstruction.
C04	Excessive inflation time	Check for air leaks.
C05	Excessive noise	Check patient condition, blood pressure cuff placement, limit patient movement.
C06	Measurement was outside of device's measurement range	Check patient condition.
E10	Blood pressure cuff overpressure condition	Check patient condition.

Table 3. Temperature

Code	Description	Corrective Action
C20	Broken/missing probe	Replace probe.
P	Loss of tissue contact	Ensure proper probe positioning.
E0.2, E0.3	Ambient temperature out of range	Adjust ambient temperature or device location.
C22	10-minute diagnostic time exceeded	Remove probe, discard probe cover, retake temperature.

Table 4. SpO_2

Code	Description	Corrective Action
E7	Internal SpO_2 error.	Retake reading.
C6	SpO_2 pulse rate out of range	Check patient condition.
C8	Faulty SpO_2 sensor.	Replace sensor.
C9	SpO_2 time limit exceeded.	Remove sensor from patient. Reapply sensor and retake reading.

Causes and Corrective Action

Table 5. Inaccurate Blood Pressure Readings

Possible Cause	Explanation and Corrective Action
Incorrect blood pressure cuff size. Use Welch Allyn approved blood pressure cuffs only.	Determine correct blood pressure cuff size. • Use reference markings on blood pressure cuff. • Measure patient's arm circumference midway between elbow and shoulder (see "Chart for Determining Blood Pressure Cuff Size" on page 23 to select correct blood pressure cuff size).
Patient's arm position	Ensure patient's arm is at heart level.
Arm movement during blood pressure cycle	Keep arm still during blood pressure cycle. • Movement may cause inaccuracies from artifact.
Blood pressure taken over clothing	Take blood pressure on a bare arm.
Arrhythmia	Check for regularity of heart rate (palpate pulse or check device). • Moderate to severe heart rate irregularities may make blood pressure difficult to measure.
Incorrect reference	Use the correct Korotkoff sound to determine diastolic blood pressure. • Many listeners incorrectly equate diastolic blood pressure with the disappearance of sound only (phase 5). The Welch Allyn Spot Vital Signs was developed using the American Heart Association recommendations, which state that phase 5 be used unless sound continues to 0 mmHg, in which case the change in the quality of sound (phase 4) is to be used. Deflate blood pressure cuff no faster than 3 mmHg per second. • One of the major sources of error in auscultatory blood pressure measurement is deflating the blood pressure cuff too quickly. The American Heart Association recommends deflation no faster than 3 mmHg per second. Only use a sphygmomanometer that is calibrated. • An uncalibrated sphygmomanometer may take inaccurate blood pressure measurements.
Change in blood pressure between auscultatory reading and Welch Allyn Spot Vital Signs reading	Check blood pressure immediately prior to Welch Allyn Spot Vital Signs reading.
Poor auscultatory sound recognition by observer	Use higher quality stethoscope. Have a different observer check patient's blood pressure.
Note: Differences of up to 10 mmHg are considered normal and occur for a number of reasons including intra-patient blood pressure variability, observer hearing differences, and auscultatory deflation rate.	

Table 6. Cuff Inflation and Deflation with No Blood Pressure Reading Displayed (or Error Code in Display)

Possible Cause	Explanation and Corrective Action
Leak in pneumatic system	Ensure all blood pressure cuff attachments are tight. Carefully check for leaks in the blood pressure cuff, tubing, and pressure hose attached to the device.
Arm movement during cycle	Keep arm still during blood pressure cycle. Movement may cause inaccuracies from artifact.
Blood pressure cuff tubing or pressure hose movement artifact	Do not contact blood pressure cuff tubing or pressure hose during blood pressure cycle. Movement may cause inaccuracies from artifact.

Table 7. No Blood Pressure Cuff Inflation

Possible Cause	Explanation and Corrective Action
Connections between device and blood pressure cuff loose	Check all connections (do not overtighten).

Table 8. Temperature Malfunction

Possible Cause	Explanation	Corrective Action
Error code displayed	Broken probe	Replace probe. Consult Service Manual. Notify biomedical department or Welch Allyn Technical Support.
Low temperature readings	Improper probe placement	Place probe in most posterior sublingual pocket when in Oral Mode. Verify patient has had nothing to eat or drink for 20 minutes.
No temperature displayed	Probe not replaced	Replace probe in holder prior to taking another temperature.

Table 9. SpO_2 Malfunction

Possible Cause	Corrective Action
Sensor in place but no SpO_2 on display	Insert the patient's finger completely into sensor. Verify blood pressure and SpO_2 measurements are not taken on the same extremity. Verify the sensor cable is correctly plugged into device. Verify you are using the correct sensor. Use only Masimo or Nellcor SpO_2 sensors and accessories with the Welch Allyn Spot Vital Signs with Masimo or Nellcor configurations, respectively.

Table 10. Device Does Not Turn On

Possible Cause	Explanation and Corrective Action
Low battery	Check connections between device and transformer, and transformer and wall receptacle.
Device not powering up	Unplug unit from wall receptacle and check for breaks in cord. If connections are secure, check electrical outlet. Charging indicator is on if connections are good and the device is plugged into a working outlet. Notify biomedical department or Welch Allyn Technical Support.

Table 11. Blood Pressure Cuff Too Tight (Over Inflation)

Possible Cause	Explanation and Corrective Action
Pressure preset too high	Check default Pressure Preset setting in internal configuration mode. Unless patient has underlying systolic hypertension, set pressure preset at 160 mmHg. (If systolic blood pressure greater than pressure preset, the device automatically increases an additional 40 mmHg.)

Table 12. Blood Pressure Cuff Pops Off

Possible Cause	Explanation and Corrective Action
Inappropriate blood pressure cuff size	Determine blood pressure cuff size with the blood pressure cuff markings or see "Chart for Determining Blood Pressure Cuff Size" on page 23. If blood pressure cuff continues to pop off, notify biomedical department or Welch Allyn Technical Support.
Blood pressure cuff applied inside out	Re-apply blood pressure cuff. Make sure Welch Allyn label is facing away from arm.

Table 13. Blood Pressure Cuff Deflating Too Slowly

Possible Cause	Explanation and Corrective Action
Normal operation	Typical time to take a reading is 20 to 45 seconds; 165 seconds is the maximum.
Pressure preset too high	Check default pressure preset setting in internal configuration mode.
Patient movement	Have patient sit still. Do not have arm tight against chest wall, as respiration may affect speed and accuracy of blood pressure measurement.
Small leak in pneumatic system	Check blood pressure cuff tubing and pressure hose for leaks.

9 Specifications

Patient Population

The Welch Allyn Spot Vital Signs is designed for use with adult and pediatric patients. Welch Allyn defines a pediatric patient as 29 days or more of age.

THE WELCH ALLYN SPOT VITAL SIGNS IS NOT INTENDED FOR USE ON NEONATES.

Welch Allyn defines neonates as children 28 days or less of age, born at term (37 weeks gestation or more), otherwise up to 44 gestational weeks.

Blood Pressure

Cuff Pressure Range	0 mmHg to 300 mmHg
Cuff Inflation Factory Default	160 mmHg
Systolic Range	60 mmHg to 250 mmHg
Diastolic Range	30 mmHg to 160 mmHg
Accuracy	Blood pressure accuracy meets or exceeds SP10-1992 AAMI standards for non-invasive blood pressure accuracy (AAMI standard: ± 5 mmHg mean error, 8 mmHg standard deviation). Blood pressure accuracy is validated for pressure measurement using the upper arm only.
Determination Time	Typical: 20 to 45 seconds Maximum: 165 seconds
Pulse Rate Range	40 bpm to 200 bpm
Pulse Rate Accuracy	±5.0%
Overpressure Cutoff	305 mmHg -0/+15 mmHg

Temperature

Accuracy	Calibration accuracy: ± 0.2° F (± 0.1° C).
Range	Maximum: 109.4° F/43.0° C Minimum: 86.0° F/30.0° C
Determination Time	Oral: approximately 4 seconds Axillary: approximately 10 seconds Rectal: approximately 15 seconds

Pulse Oximetry

Masimo Sensor Accuracy Guide

Accuracy specified when used with Masimo SET pulse oximetry monitors or with licensed Masimo SET pulse oximetry modules using Masimo patient cables, during no motion. Numbers present ± 1 standard deviation. Plus or minus one standard deviation represents 68% of the population. SpO_2 accuracy from 70% to 100%. Pulse rate accuracy from 25 to 240 bpm.

Performance Measurement Range	SpO_2: 70 to 100% Pulse Rate: 25 - 240 beats per minute (BPM)
Perfusion	0.02% to 20%
SpO_2 Accuracy	Saturation: 70% to 100% No Motion: Adults, Pediatrics ± 2 digits Motion: Adults, Pediatrics ± 3 digits Low Perfusion: Adults, Pediatrics ± 2 digits
Pulse Rate Accuracy	Pulse Rate: 25 to 240 bpm No Motion: Adults and Pediatrics ± 3 digits Motion: Adults and Pediatrics ± 5 digits Low Perfusion: Adults and Pediatrics ± 3 digits

Table 14. Masimo Sensor Accuracy Guide

		Saturation Accuracy		Pulse Rate Accuracy	
Sensor	**Weight Range**	**No Motion**	**Motion**	**No Motion**	**Motion**
LNCS-DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNCS-DCIP	10 to 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNCS-ADTX	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNCS-PDTX	10 to 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNCS INF-L	3 to 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-DCIP	10 to 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-ADT	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-PDT	10 to 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP INF-L	3 to 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm

Masimo Patents

The Masimo sensors and cables are covered under one or more of the following U.S.A. patents: 5,758,644; 5,823,950; 6,011,986; 6,157,850; 6,263,222; 6,501,975; and other applicable patents listed at www.masimo.com/patents.htm.

Nellcor® Sensor Accuracy Guide

Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified saturation SpO_2 range. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as + "X" digits. This variation equals plus one standard deviation (+ 1 SD), which encompasses 68% of the population.

Pulse Rate Range	25 to 240 bpm
Pulse Rate Accuracy	±3 bpm ±3 bpm (low perfusion)

Table 15. OxiMax Sensor Models, Single Patient Use

Sensor Models	SpO_2 Range 70% to 100%
MAX-AI	± 2
MAX-PI	± 2
MAX-II	± 2
MAX-RI[1]	± 3.5

[1] The accuracy specification has been determined between saturations of 80% to 100%.

Table 16. OxiCliq Sensor Models, Single Patient Use

Sensor Models	SpO_2 Range 70% to 100%
OXICLIQ-PI	± 2.5

Table 17. Reusable Sensor Models

Sensor Models	SpO_2 Range 70% to 100%
D-YS (Infant to Adult)	± 3
D-YS and D-YSE	± 3.5
D-YS and D-YSPD	± 3.5
DS-100A	± 3
OXI-A/N (Adult)	Adult: ± 3
OXI-P/I (Pediatric/infant)	± 3

Nellcor Patents

Covered by one or more of the following US Patents: 4,802,486; 4,869,254; 4,928,692; 4,934,372; 5,078,136; 5,351,685; 5,485,847; 5,533,507; 5,577,500; 5,803,910; 5,853,364; 5,865,736; 6,083,172; 6,708,049; Re. 35,122 and foreign equivalents.

Mechanical

Dimensions	Height: 9.7 inches (24.6 cm) Length: 5.7 inches (14.5 cm) Depth: 4.7 inches (12.0 cm)
Weight	Approximately 4.6 pounds (2.2 kg)
Mounting	Self-supporting on rubber feet Custom Mobile Stand Custom Wall Mount Custom IV Pole Mount
Portability	May be hand-carried when held by the rear handle.

Electrical

Power Requirements	Patient-rated isolation transformer is connected to AC mains: North American Version:120VAC, 60Hz. 0.13A Input, 7.2VDC, 1.0A Output International Version:240VAC, 50Hz 0.065A Input, 7.2VDC, 1.0A Output Australian Version:240VAC, 50Hz, 13VA Input, 7.2VDC, 1.0A Output
Battery	Lead acid, with external charger. A fully charged battery supports 130 typical blood pressure determinations taken at 7-minute intervals. The battery is 90-100% charged after 12 hours of charging. The battery automatically charges when the Spot Vital Signs is powered through the AC power transformer. The battery charges faster when the instrument is not in operation.

Environmental

Operating Temperature	+10° to +40° C (Thermometer operating temperature 16° to 40° C) +50° to +104° F (Thermometer operating temperature 61° to 104° F)
Storage Temperature	-20° to +50° C -4° to +122° F
Transport Temperature	-20° to +49° C -4° to +122° F
Relative Humidity	15 to 90% (non-condensing)
Operating Altitude	-170 to +4877 m -557 to +16,000 ft.

Guidance and Manufacturer's Declaration

Emissions and Immunity Information

Electromagnetic Emissions

The 420 Series Spot Vital Signs is intended for use in the electromagnetic environment specified below. The customer or user of the 420 Series Spot Vital Signs should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The 420 Series Spot Vital Signs uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 420 Series Spot Vital Signs is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The 420 Series Spot Vital Signs is intended for use in the electromagnetic environment specified below. The customer or user of the 420 Series Spot Vital Signs should assure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 420 Series Spot Vital Signs requires continued operation during power mains interruptions, it is recommended that the 420 Series Spot Vital Signs be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic Immunity

The 420 Series Spot Vital Signs is intended for use in the electromagnetic environment specified below. The customer or user of the 420 Series Spot Vital Signs should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the 420 Series Spot Vital Signs including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 3 Vrms	$d = (1.17)\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1 = 3 V/m	$d = (1.17)\sqrt{P}$ 80 MHz to 800 MHz $d = (2.33)\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 420 Series Spot Vital Signs is used exceeds the applicable RF compliance level above, the 420 Series Spot Vital Signs should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 420 Series Spot Vital Signs.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the 420 Series Spot Vital Signs

The 420 Series Spot Vital Signs is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 420 Series Spot Vital Signs can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 420 Series Spot Vital Signs as recommended below, according to the maximum output power of the communications equipment.

	Separation Distance According to Frequency of Transmitter (m)		
Rated Max. Output Power of Transmitter (W)	**150 kHz to 80 MHz** $d = (1.17)\sqrt{P}$	**80 MHz to 800 MHz** $d = (1.17)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (2.33)\sqrt{P}$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Patents

D392,043 and other patents pending.

Agency Approvals

C US
166292

CERTIFIED TO: CAN/CSA STD C22.2 NO. 601.1

CONFORMS TO: IEC 60601, UL STD 60601-1

N344

Welch Allyn PTY, Ltd - Australia
Metro Centre
Unit 5/38 South Street
Rydalmere NSW 2116, Australia

EMC Framework of Australia

CE 0297

The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive.

EC REP

Authorized European Representative Address:

European Regulatory Manager
Welch Allyn Ltd.
Navan Business Park
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Navan, County Meath, Republic of Ireland
Tel.: +353 46 90 67700 • Fax: +353 46 90 67756

10 Maintenance

Welch Allyn will make available,upon request, circuit diagrams and other information which will assist appropriately qualified technical personnel in repair of this device. Please reference “4200-89E” on page 61.

Cleaning

Spot Vital Signs

Caution Do not use ethyl alcohol to clean the Spot Vital Signs device.

Caution Do not sterilize or autoclave the Spot Vital Signs.

Occasionally wipe the Spot Vital Signs, as necessary, with a cloth slightly dampened with appropriately diluted, non-staining disinfectant solution. Use either 70% isopropyl alcohol, 10% chlorine bleach solution, or mild detergent in warm water. Never immerse the Spot Vital Signs in any type of fluid.

Note Prevent water or other fluids from entering any connectors. Should this occur, dry the connectors with warm air. Check all measurement functions for proper operation.

Blood Pressure Cuff

Caution Do not press with a hot iron.

Clean the blood pressure cuff with a damp cloth, or wash in water with soap or detergent. Before washing the blood pressure cuff, remove the tube fitting(s), close off tubes with plugs (available as accessory 5082-163) and place the hook and loop fasteners in the closed position. After washing, allow the blood pressure cuff to air dry. Re-assemble the tube fitting(s).

Disinfection: You may use glutaraldehyde-type liquid disinfectants on the durable blood pressure cuff. Prolonged use of these disinfectants at full strength may cause discoloration of the white blood pressure cuff markings.

Sterilization: Do not use steam or heat to sterilize the blood pressure cuff or pressure hose. If necessary, use gas sterilization.

Cables and Pressure Hose

Wipe the cabling and pressure hose with a damp cloth moistened in a mild detergent solution. Do not immerse.

Temperature Probe

Periodically wipe the temperature probe clean with an alcohol-dampened cloth, warm water, or properly diluted, non-staining disinfectant. Do not immerse the probe.

SpO_2 Sensor

WARNING Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connections are not waterproof). Do not use irradiation, steam, or ethylene oxide for sterilization.

Clean the reusable SpO_2 sensor with a 70% isopropyl alcohol solution and allow to air dry. Do not immerse the sensor or cable.

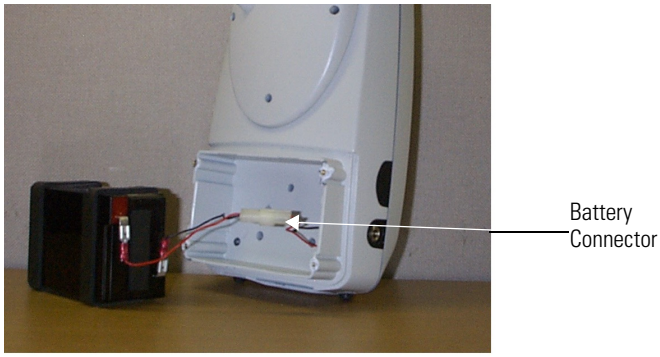
Every 3 months, inspect the temperature probe, SpO_2 cord, and accessories for fraying or other damage. Replace as necessary.

Battery Removal and Replacement

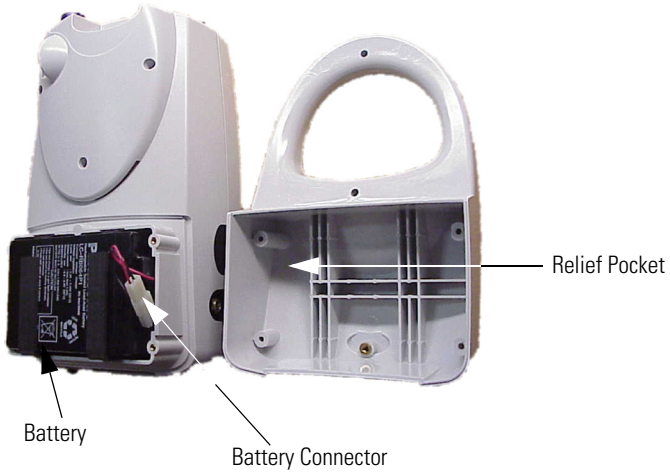
Caution Only use the Welch Allyn 4200-84 lead acid battery. Using the incorrect battery will cause damage to the Spot Vital Signs and void the warranty.

As necessary, replace the internal battery after heavy use or the battery no longer charges. Use a battery with the same part number.

1. Turn the Spot Vital signs off and disconnect the AC power transformer cord.
2. Remove the 4 screws holding the battery door using a phillips-head screwdriver. Remove the battery door to expose the battery.
3. Tip the Spot Vital Signs to slide the battery out. Disconnect and discard the old battery per local regulations. Reconnect the new battery as shown as quickly as possible to prevent loss of power to the unit and subsequent loss of clock time.



4. Slide the new battery completely into the compartment. Lay the connector on the battery. The relief pocket in the battery door purposely provides sufficient clearance for the battery connector.



5. Replace the battery door and tighten each of the 4 screws.
6. Connect the AC power transformer to the Spot Vital Signs and charge the new battery for 16 hours. It is possible to use the Spot Vital Signs during this charging period.

The battery is a lead-acid battery. In the USA, call 1-800-SAV-LEAD for instructions on how to recycle. For users outside the US please contact your local authorities on recycling.

Masimo SpO_2 Calibration Check

Use a Masimo-approved SpO_2 simulator (Fluke Biotek Index 2 or Clinical Dynamics SmartSat) to check the SpO_2 accuracy. There is no way to change the calibration of the SpO_2 module. If the SpO_2 is out of calibration, contact Technical Service.

Nellcor SpO_2 Functional Check

Use a Nellcor SpO_2 simulator (SRC-MAX) to check the SpO_2 functionality. There is no way to change the functionality of the SpO_2 module. If the SpO_2 is not functioning properly, contact Technical Service.

SpO_2 Accessory Disposal

Dispose of all finger sensors and cables in accordance with facility, local, and goverment regulations.

Temperature Calibration Check

Use the 9600 Plus Calibration Tester to check the SureTemp thermometer accuracy. If the thermometer is out of calibration, contact Technical Service.

Service Manual/Spare Parts

A Service Manual is available upon request to qualified electronic personnel. The Service Manual is a comprehensive guide to troubleshooting, service, and repair of the Spot Vital Signs.

Also included with the Service Manual is a complete spare parts list. Order spare parts from your local Welch Allyn Service Center listed on page ii.

Service Loaners

Service loaners are provided, on request, when a Welch Allyn Service Center provides service. Loaners for products repaired while under the original warranty, or while under extended warranty or service contract, are provided free of charge and are shipped within 48 hours of notification of need. Welch Allyn pays the shipment charges.

For service repairs outside of warranty or contract, loaners are available for a nominal daily charge and shipment. This is subject to availability. Loaners are shipped pre-paid; however, this charge is added to the service charges.

Service Policy

A Welch Allyn Service Center must approve and perform all repairs on products under warranty. *Unauthorized repairs will void the warranty*. Qualified electronics personnel or a Welch Allyn service center should repair products out of warranty.

Technical Assistance

If you have an equipment problem that you cannot resolve, call the Welch Allyn Service Center nearest you during normal business days at the phone numbers listed on page ii.

If you are advised to return a product to Welch Allyn for repair or routine maintenance, schedule the repair with the service center nearest you.

Before returning a product for repair, you must obtain authorization from Welch Allyn. Our service personel will give you a Service Notification number. Note this number on the outside of your shipping box. Service centers will not accept returns without a Service Notification number for delivery.

11 Supplies and Accessories

Latex-Free Blood Pressure

Table 1. Cuff and Bag Combination

Catalog #	Description	Catalog #	Description
5200-01	Cuff and bladder, adult, one tube	5200-10	Cuff and bladder, thigh, one tube
5200-02	Cuff and bladder, large adult, one tube	5200-03	Cuff and bladder, child, one tube

Table 2. One-Piece Cuff

Durable Cuff		Disposable Cuff	
Catalog #	**Description**	**Catalog #**	**Description**
5082-203-3	One-piece cuff, small child, one tube	5082-93-3	One-piece cuff, small child, one tube (box of 5)
5082-204-3	One-piece cuff, child, one tube	5082-94-3	One-piece cuff, child, one tube (box of 5)
5082-205-3	One-piece cuff, small adult, one tube	5082-95-3	One-piece cuff, small adult, one tube (box of 5)
5082-206-3	One-piece cuff, adult, one tube	5082-96-3	One-piece cuff, adult, one tube (box of 5)
5082-207-3	One-piece cuff, large adult, one tube	5082-97-3	One-piece cuff, large adult, one tube (box of 5)
5082-208-3	One-piece cuff, thigh adult, one tube	5082-98-3	One-piece cuff, thigh, one tube (box of 5)

Table 3. Replacement Cuffs and Bladders

Catalog #	Description	Catalog #	Description
5200-04	Adult Bladder, one tube	5082-01	Adult cuff (sleeve)
5200-05	Large Adult Bladder, one tube	5082-16	Large adult cuff (sleeve)
5200-06	Child Bladder, one tube	5082-18	Child cuff (sleeve)
5200-11	Thigh Bladder, one tube	5082-64	Thigh cuff (sleeve)

Table 4. Miscellaneous Blood Pressure Accessories

Catalog #	Description	Catalog #	Description
5200-12	Straight Pressure Hose (8ft./2.4M)	5200-08	Calibration T-Connector
5200-19	Straight Pressure Hose (5ft./1.5M)		

Pulse Oximetry Accessories and Supplies

Masimo

Table 5. Adhesive Sensors: Single-Patient Use

Catalog #	Description	Weight Range
LNCS-ADTX	Adhesive Finger Sensor - Adult (20 per case)	>30 kg
LNCS-PDTX	Adhesive Finger Sensor - Pediatric (20 per case)	10 to 50 kg
LNCS INF-L	Adhesive Finger Sensor - Infant (20 per case)	3 to 20 kg
LNOP-ADT	Adhesive Adult sensor (20 per case)	>66 lbs (30 kg)
LNOP-PDT	Adhesive Pediatric sensor (20 per case)	22 to 110 lbs (10 to 50 kg)
LNOP INF-L	Adhesive Infant sensor (20 per case)	3 to 20 kg

Table 6. Reusable Sensor

Catalog #	Description	Weight Range	Quantity
LNCS-DCI	Finger sensor - adult	>66 lbs (30 kg)	1
LNCS-DCIP	Finger sensor - pediatric	10 to 50 kg	1
LNOP-DCI	Finger sensor - adult	>66 lbs (30 kg)	1
LNOP-DCIP	Finger sensor - pediatric	10 to 50 kg	1

Table 7. Sensor Cables

Catalog #	Description	Weight Range	Quantity
LNC-4-WA	4-foot cable with DB-9 connector for LNCS	NA	1
LNC-10-WA	10-foot cable with DB-9 connector for LNCS	NA	1
PC-04-WA	4-foot cable with DB-9 connector for LNOP	NA	1
PC-08-WA	8-foot cable with DB-9 connector for LNOP	NA	1

Nellcor

Table 8. OxiMax Adhesive Sensors: Single-patient use

Catalog #	Description	Weight Range	Quantity
MAX-AI	Adult sensor	>30 kg	24
MAX-PI	Pediatric sensor	10 - 50 kg	24
MAX-II	Infant sensor	3-20 kg	24
MAX-RI	Adult nasal sensor	>50 kg	24
SRC-MAX	Portable oximetry tester		

Table 9. OxiMax OxiCliq® Sensors: Reusable cable

Catalog #	Description	Weight Range	Quantity
OC-3	OxiCliq sensor cable (3 ft)		1
OXICLIQ PI	Pediatric oxygen transducer, user with OC-3 cable	10 - 50 kg	Case of 24

Table 10. OxiMax Reusable Sensors

Catalog #	Description	Weight Range	Quantity
DS-100A	Durasensor® adult oxygen transducer	>40 kg	1
OXI-A/N	Oxiband® OXI-A/N, adult/neonatal* transducer	<3 kg or >40 kg	1 sensor/50 wraps
OXI-P/I	Oxiband OXI-P/I, pediatric/infant transducer	3 - 40 kg	1 sensor/50 wraps
D-YS	Dura-Y® oxygen transducer	>1 kg	1 sensor/40 wraps
D-YSE	Ear clip (use with Dura-Y sensor)	>30 kg	1
D-YSPD	PediCheck™ pediatric spot-check sensor (use with Dura-Y sensor)	3 - 40 kg	1

Table 11. OxiMax Sensor Cables

Catalog #	Description	Quantity
DEC-4	SpO_2 extension cable, 4 ft.	1
DEC-8	SpO_2 extension cable, 8 ft.	1

* The Welch Allyn Spot Vital Signs is not intended for use on neonatal patients.

Temperature

Table 12. Accessories and Supplies

Catalog #	Description	Catalog #	Description
02678-100	Oral/axillary probe (9ft./2.7M)	05031-110	Disposable probe covers (10,000 covers, 25/box)
02679-100	Rectal probe (9ft./2.7M)	06137-000	Temperature Calibration Key
05031-101	Disposable probe covers (1,000 covers, 25/box)	01802-110	Model 9600 Plus Calibration Tester

Mounting

Table 13. Accessories and Supplies

Catalog #	Description	Catalog #	Description
4200-60	Mobile Stand	4200-64	IV Pole Mount
4200-62	Wall Mount	4200-70	Anti-Theft Kit

Extended Warranty

Table 14. One-year extended warranty

Catalog #	Description	Catalog #	Description
4200-00B	Model 4200B	4200-M0B	Model 42M0B
4200-OTB	Model 420TB	4200-NTB	Model 42NTB
4200-N0B	Model 42N0B	4200-MTB	Model 42MTB

Miscellaneous

Table 15. Accessories and Supplies

Catalog #	Description	Catalog #	Description
4200-84	Lead Acid Battery	5200-101A	AC Power Transformer (US/Canada/Japan)-120V, 60Hz
4200-87X*	Directions for Use	5200-103A	AC Power Transformer (Europe/UK) -240V, 50Hz
4200-88X*	Quick Reference/Error Code Card	5200-103Z	AC Power Transformer (Australia) - 240V, 50Hz
4200-155	Inservice CD (English only)	76400	Line Cord (US/Canada/Japan)
4200-89E	Service Manual (English only)	76402	Line Cord (Europe)
4200-100	Carrying Case	76404	Line Cord (UK)
4200-170	Connectivity Accessory Kit	76406	Line Cord (Australia)
53600	Printer paper (24 rolls)	4200-250	Pediatric accessory kit (small child, child, small adult cuffs and Nellcor SpO_2 sensor)
53600B	Printer paper (4 rolls)	4200-350	Pediatric accessory kit (small child, child, small adult cuffs and Masimo SpO_2 sensor)

* Replace the "X" with the following letter abbreviation to order the appropriate language manual.

Table 16. Printed Material Language List

Language Abbreviation	Language	Language Abbreviation	Language	Language Abbreviation	Language
E	English	G	Deutsch	PO	Polish
C	Chinese	I	Italiano	P	Português
DK	Dansk	N	Norsk	S	Español
F	Français	NL	Nederlands	SW	Svensk
FI	Suomi				

Warranty

Spot

Welch Allyn warrants Spot Vital Signs, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of two years from the date of purchase from Welch Allyn or its authorized distributors or agents. The battery is covered by a one-year warranty against original defects in material or workmanship. Welch Allyn will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return Spot Vital Signs to Welch Allyn or an authorized distributor, agent, or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by other than Welch Allyn or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

Remember to submit the instrument registration/warranty card for warranty validation. Complete the information and mail the pre-addressed card to Welch Allyn.

Accessories

The Masimo finger sensor and cable are covered by a six-month warranty against original defects in material or workmanship.

The Nellcor DS-100A is covered by a one-year warranty and the Nellcor DEC-4 cable is covered by a three-month warranty against original defects in material or workmanship.

The Reusable Two-Piece Blood Pressure Cuff is covered by a two-year warranty against original defects in material or workmanship.

The SureTemp probe is covered by a one-year warranty against original defects in material and workmanship. Probe covers are intended for single-use only.

Welch Allyn®

Advancing Frontline Care™

Reorder No. 4200-87E
Material No. 706272 Ver. C